

REMARKS

Claims 1-25 are pending in this application. Claims 22-25 have been withdrawn from consideration and claims 1-21 have been rejected.

RESTRICTION REQUIREMENT

The Office has maintained the restriction requirement, despite Applicant's arguments to the contrary. The Office accordingly made the restriction requirement final. Applicant continues to disagree for the reasons of record, but recognizes the finality of that requirement.

DRAWINGS

The Office has objected to the drawings because their image quality is not clear and has required new drawings. In response, Applicant submits the replacement sheets of drawings which are attached to this Amendment. Applicant accordingly requests withdrawal of this objection.

SPECIFICATION

The Office has objected to the specification for the reasons detailed on pages 3-4. The Office first objects to the specification because of the misspelling in paragraph [0030]. Applicant has accordingly corrected paragraph [0030].

The Office has also objected to the specification since, in brief, it supposedly does not contain disclosure adequate for the means-plus-function limitations in claims 2, 6, 11, and 17. Applicant disagrees that the specification does not contain an adequate disclosure since the

skilled artisan would have understood these claim limitations in light of the specification. Solely in an effort to expedite prosecution, though, Applicant has amended the claims to remove the means-plus-function limitations. Accordingly, Applicant respectfully requests withdrawal of this objection.

35 U.S.C. § 112

The Office has rejected claims 9-14 under 35 U.S.C. § 112, ¶ 2, as being indefinite for the reasons set forth on page 4 of the Office Action. Applicant thanks the Office for the careful reading of the claims. Applicant believes that proper antecedent basis existed for the term a shaft, especially when the claims were read in light of the specification. Solely in an effort to expedite prosecution, though, Applicant has amended the claims to distinguish between the shaft members (of the tunneler tip) and the shaft (of the tunneler). Accordingly, Applicant respectfully requests withdrawal of this rejection.

35 U.S.C. § 102

The Office has rejected claims 1-20 under 35 U.S.C. § 102(b) as being anticipated by Wilson et al. (U.S. Patent Application No. 2002/0099327) for the reasons noted on pages 5-6. Applicant respectfully traverses this rejection.

The Office argues that Wilson et al. describe a device that contains all of the features recited in the rejected claims. In particular, the Office argues that Wilson et al. describe a multi-lumen catheter that is "capable of being used as a tunneler." Such an argument, however, is not supported in the disclosure of Wilson et al.

Wilson et al. describe in several instances that the catheter 12 is pulled through a tunnel that has already been created in the desired location of the patient. First, the Abstract notes that a subcutaneous tunnel is created and the first end of the tunnel is near the incision, and “then” the catheter tube 12 is routed through the tunnel. Second, paragraph [0007] describes that a subcutaneous tunnel is created and then the catheter tube is routed from the first end through the second end of the tunnel. Third, paragraph [0038] describes that a tunnel of 8 cm to 10 cm should be created by means of “a tunneler” and then the catheter tube 12 is gently pulled through the tunnel. Finally, claim 1 notes that a subcutaneous tunnel is created and then the catheter tube is routed through the tunnel. In light of all of these disclosures, the skilled artisan would have come to the inescapable conclusion that a tunnel is created by a tunneler before the catheter tube 12 is inserted in the tunnel. Thus, the skilled artisan would have concluded that, contrary to the Office’s allegation, the catheter tube is not “used as a tunneler.”

The Office also argues that Wilson et al. describe a gripping means (38, 40). Again, Applicant submits that the Office has misinterpreted the disclosure of Wilson et al. Wilson et al. describe that the hub body 21 (which is connected to the catheter tube 12 after it is pulled through the tunnel) contains two suture wings 38 and 40 which are used to suture the catheter assembly 10 to the patient in the desired located after the catheter has been inserted. See *paragraphs [0022] and [0039]*. And the Office has not substantiated how the suture wings of a hub body—that are attached to the catheter after it has already been pulled through a tunnel—could be considered as a grip for the tip of a tunneler.

The Office also argues that Wilson et al. contain a protrusion 21(a) located on the outside of shaft members (14, 16) that retains the members in the lumen of the catheter 12. Yet again, Applicant submits that the Office has misinterpreted the disclosure of Wilson et al. Wilson et al.

describe that the female threaded portion of the connector cover 34 receives the male threaded portion 21(a) of the hub body 21 to attach the hub assembly 20 to the catheter tube 12. *See paragraph [0040].* In light of this disclosure, the skilled artisan would have understood that the male threaded portion 21(a) is used to connect the hub body 21 to the catheter. And the Office has not substantiated how such a disclosure would describe a protrusion on shaft members of a tunneler tip that retain those members in the lumen of a catheter.

The Office also argues that Wilson et al. discloses a shaft (12) that is removably connected to a tip (20). Such an argument ignores the fact that the rejected claims require a shaft of a tunneler, but that Wilson et al. expressly describe element 12 as a catheter. As well, it ignores the fact that Wilson et al. describe element 20 as a hub that is attached to the catheter 12 after it is pulled through a tunnel, not a tip of a tunneler that is used to create the tunnel.

Thus, the Office has not shown that Wilson et al. teach every limitation in the rejected claims. Accordingly, Applicant respectfully requests withdrawal of this ground of rejection.

35 U.S.C. § 103

The Office has rejected claim 21 under 35 U.S.C. § 103 as being unpatentable over Durand (U.S. Patent No. 5405329) in view of Wilson et al. for the reasons noted on pages 7-8. Applicant respectfully traverses this rejection.

The Office admits that Durand does not teach a tunneler portion that contains multiple shaft, but argues that it would have been obvious to modify the device of Durand with the multiple-lumen catheter of Wilson et al. in order to keep the two catheters separate through the tunnel and prevent having them twist. Such an argument again ignores the simple fact—as detailed above—that Wilson et al. do not teach a tunneler.

As well, the Office's proposed combination of references fails to provide motivation sufficient to establish a *prima facie* case of obviousness. To meet this burden, the Office must show some teaching, suggestion, or motivation to make the proposed modification found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *M.P.E.P.* § 2143.01. But the Office merely provides the motivation without pointing to where in the prior art or the skilled artisan's knowledge such motivation originates. As such, the Office has not established a *prima facie* case of obviousness.

Thus, the Office has not shown that the proposed combination of references teaches or suggests each and every limitation in the rejected claims. Accordingly, Applicant respectfully requests withdrawal of this ground of rejection.

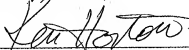
CONCLUSION

For the above reasons, Applicant respectfully requests the Office to withdraw the pending grounds of rejection and allow all the pending claims.

If there is any fee due in connection with the filing of this Amendment, including a fee for any extension of time not accounted for above, please charge the fee to our Deposit Account No. 50-0843.

Respectfully Submitted,

By



KENNETH E. HORTON

Reg. No. 39,481

Date: October 13, 2006